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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Bandarage et al**

Application No: **10/603,098**

Group Art Unit: **1626**

Filed: **June 25, 2003**

Examiner: **L. L. Stockton**

For: **Cyclooxygenase-2 Selective Inhibitors, Compositions and Methods of Uses**

Attorney Docket No: **102258.154 US1**

Commissioner of Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Provisional Response to Restriction Requirement and  
Request for Reconsideration of Restriction Requirement Under 37 C.F.R. § 1.143**

**I. Introductory Comments**

This response is submitted in reply to the Restriction Requirement dated December 10, 2004, for which a response is due on or before January 10, 2005.

No fee is believed to be due; however, the Commissioner is authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 08-0219 to maintain the pendency of the present application.

**II. Request for Reconsideration of Restriction Requirement**

Under 37 C.F.R. §1.143, Applicants respectfully request reconsideration of the restriction requirement dated May 27, 2004.

The examiner restricted the invention as follows:

|           |                                  |   |
|-----------|----------------------------------|---|
| Group I   | Claims 1, 2, 14-16, 28-39 and 55 | Compounds and compositions of Formula I or Formula II wherein R <sub>1</sub> is -S(O) <sub>2</sub> -CH <sub>3</sub> |
| Group II  | Claims 1, 2, 14-16, 28-39 and 55 | Compounds and compositions of Formula I or Formula II wherein R <sub>1</sub> is -S(O) <sub>2</sub> -NH <sub>2</sub> |
| Group III | Claims 1, 2, 14-16, 28-39 and 55 | Compounds and compositions of Formula III wherein R <sub>1</sub> is -S(O) <sub>2</sub> -CH <sub>3</sub>             |

**Provisional Response to Restriction Requirement**

**Application No. 10/603,098**

**Page 2 of 4**

|            |                                  |  |
|------------|----------------------------------|--|
| Group IV   | Claims 1, 2, 14-16, 28-39 and 55 | Compounds and compositions of Formula III wherein $R_1$ is $-S(O)_2-NH_2$              |
| Group V    | Claims 3-13, 17-27, 40-50        | Methods of use for products of Formula I or Formula II wherein $R_1$ is $-S(O)_2-CH_3$ |
| Group VI   | Claims 3-13, 17-27, 40-50        | Methods of use for products of Formula I or Formula II wherein $R_1$ is $-S(O)_2-NH_2$ |
| Group VII  | Claims 3-13, 17-27, 40-50        | Methods of use for products of Formula III wherein $R_1$ is $-S(O)_2-CH_3$             |
| Group VIII | Claims 3-13, 17-27, 40-50        | Methods of use for products of Formula III wherein $R_1$ is $-S(O)_2-NH_2$             |
| Group IX   | Claims 51-54                     | Kits comprising products of Formula I or Formula II wherein $R_1$ is $-S(O)_2-CH_3$    |
| Group X    | Claims 51-54                     | Kits comprising products of Formula I or Formula II wherein $R_1$ is $-S(O)_2-NH_2$    |
| Group XI   | Claims 51-54                     | Kits comprising products of Formula III wherein $R_1$ is $-S(O)_2-CH_3$                |
| Group XII  | Claims 51-54                     | Kits comprising products of Formula III wherein $R_1$ is $-S(O)_2-NH_2$                |
| Group XIII | Claim 55                         | Products not embraced by Groups I or II  |

The claims in the pending application are directed to compounds and compositions comprising **nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds**, kits comprising nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds, and the methods of use for the compounds and/or compositions.

**III. Restriction is Not Proper When the Claims are Related**

As stated in MPEP §808.02, “[w]here, as disclosed in the application, the several inventions claimed are related, and such related inventions are not patentably distinct as claimed, restriction under 35 U. S. C. §121 is never proper (MPEP §806.05).”

All the pending claims are related. Thus, the restriction requirement is not proper. To show that the inventions are distinct, the Examiner must show either that (1) there is a separate classification of the claims; (2) a separate status in the art when they are classifiable together; or (3) a different field of search. *In re Kase*, USPQ2d 1063 (US PTO Director, 2004).

None of these three criteria have been shown with the claims of this application:

If the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds and compositions are allowable, then all the kits and methods of use for these compositions would also be allowable. In other words, every pending claim that requires a **nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compound** would also be allowable. *In re Kase*, USPQ2d 1063 (US PTO Director, 2004).

A search of the prior art for the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds and compositions would necessarily encompass a search of the prior art for their methods of use and the kits comprising the compounds. Thus, the prior art for the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds and compositions of Groups I-IV of Formulas I-III respectively, will also be the same prior art for their methods of use and kits for the compositions comprising the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds (i.e., Groups IV-XIII ).

### **III. Proposed restriction requirement**

Applicants respectfully propose the following restriction requirement:

|           |                       |  |
|-----------|-----------------------|--|
| Group I   | Claims 1-55 (in part) | Compounds, compositions, kits and methods of use for Formula I   |
| Group II  | Claims 1-55 (in part) | Compounds, compositions, kits and methods of use for Formula II  |
| Group III | Claims 1-55 (in part) | Compounds, compositions, kits and methods of use for Formula III |

### **IV. Provisional Response to Restriction Requirement**

Applicants provisionally elect Group IV, claims 1, 2, 14-16, 28-39 and 55 drawn to the compounds and compositions of Formula III wherein R<sub>1</sub> is -S(O)<sub>2</sub>-NH<sub>2</sub>, with traverse.

### **V. Election of Species**

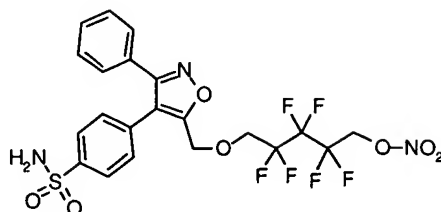
In response to the election of species requirement, Applicants elect the nitrosated cyclooxygenase inhibitor of Formula A, 4-(5-((2,2,3,3,4,4-hexafluoro-5-(nitrooxy)pentyl)oxy)methyl)-3-phenylisoxazol-4-yl)benzenesulfonamide, with traverse.

This compound has the structure:

**Provisional Response to Restriction Requirement**

**Application No. 10/603,098**

**Page 4 of 4**



(A)

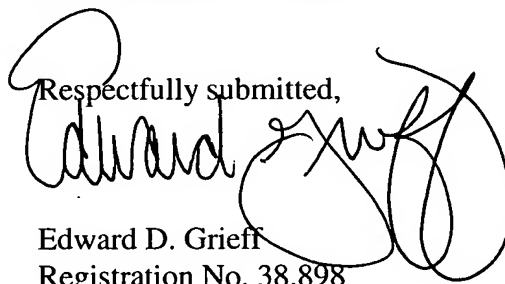
The synthesis of this compound is described in Example 34 of the specification at page 99, line 15 to page 100, line 13.

**VI. Conclusion**

Applicants respectfully request that the restriction requirement be withdrawn and be replaced with Applicant's proposed restriction requirement.

An early and favorable consideration and allowance of the pending claims is respectfully requested.

Respectfully submitted,



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Date: January 10, 2005  
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